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UNCLAS SECTION 01 OF 02 ANKARA 000839

SIPDIS

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SENSITIVE

E.O. 12958: N/A
TAGS: ETRD KIPR TU
SUBJECT: GOT Defends New Data Exclusivity Regulation and Reports System for Patent Linkage

SENSITIVE BUT UNCLASSIFIED. PLEASE HANDLE ACCORDINGLY.

REF: (A) State 19340 (B) Ankara 394
(C) State 23950

Summary

¶1. (SBU) Health Ministry and Foreign Trade Undersecretariat representatives argued that Turkey's new data exclusivity regulation goes as far as is legally possible to protect research-based companies within Turkey's legal framework. The Health Ministry reported that it had implemented a system for ensuring that generic registration applications for patented drugs are not accepted. End Summary.

Data Exclusivity Demarche

¶2. (SBU) Econoff and Econ Specialist met with Orhan Gumrukoglu, the Health Ministry's Director General for Pharmaceuticals, on February 10 to deliver ref (A) demarche outlining U.S. concerns with Turkey's January 19 data exclusivity regulation (ref B). Gumrukoglu responded that Turkey had gone as far as it could go in providing limited retroactive protection for research-based companies. He maintained that generic companies would flood the Turkish court system with challenges if the GOT were to retroactively provide data exclusivity in cases in which generic copy applications had already been filed. This would hurt the research-based companies by tying up implementation of the entire regulation, possibly for years. Gumrukoglu asserted that the GOT would fully implement the protections in the regulation, and planned to increase the term of protection from six to ten years when Turkey joins the European Union.

¶3. (SBU) Gumrukcuoglu stated that he was aware of at least 118 molecules with license applications in Europe, but not in Turkey, filed before 2005; all of these drugs could enjoy retroactive protection. In response to Econoff's question as to how many Turkish generic applications had been filed before 2005 for molecules which would otherwise be entitled to retroactive data exclusivity protection, Gumrukoglu stated that there were perhaps 30 to 50 such molecules. However, there might be multiple generic applications for the same molecule. Note: Research-based industry has said that there are hundreds, perhaps even 1,000 or more, data exclusivity-infringing applications in the Health Ministry pipeline. End Note.

¶4. (SBU) Gumrukoglu predicted that the January regulation would be a boon to research-based companies. He estimated that they would realize an extra one billion USD in sales over the next three or four years, and that this would create exceptional fiscal strain in connection with Turkey's IMF program since some 90 percent of this would be publicly-funded. Note: Research-based industry has claimed that the overall impact, especially for the GOT budget, will be far smaller. End Note.

¶5. (SBU) In response to Econoff's caution that continuing gaps in data exclusivity protection would be a major issue in this spring's Special 301 review, Gumrukoglu emphasized that the GOT had done all that it could on this issue and expressed the hope that the USG would recognize Turkey's efforts in this area.

¶6. (SBU) Econ Counselor and Econoff also delivered ref (A) demarche to Tevfik Mengu, Foreign Trade's Director General for Agreements, on February 11. We highlighted the inconsistency of the loopholes in the new

regulations with the commitments Turkey made when it joined TRIPS, as well as the difficulties they created for expanding bilateral trade and investment. Mengu noted that Turkey did not share the U.S. interpretation of TRIPS Article 39 and echoed the Health Ministry's opinion that doing more on retroactivity is legally impossible. He said that GOT agencies are considering further amendments to the legislation that might address the concerns raised in our demarche. However, he did not hold out any hope that "the lawyers" would be able to find a way around the legal problem.

Patent Linkage

¶7. (U) Recalling the Ambassador's discussion with the Health Minister in December 2004 on the patent linkage issue, Gumrukoglu reported that as of January 1, the Health Ministry and Turkish Patent Institute (TPI) have established a system to prevent generic registration of molecules entitled to patent protection. Gumrukoglu stated that new generic applications must be accompanied by correspondence from TPI stating that there is no valid Turkish patent on the drug. He said the Health Ministry would check with TPI if there were any reason to doubt whether an approval would infringe a Turkish patent. He also told us he had asked the Research-Based Pharmaceuticals Association (Turkish acronym AIFD) for a list of patented drugs in Turkey.

¶8. (SBU) Gumrukoglu implied that this system has no impact on Eli Lilly's efforts to block registration of generic copies of Zyprexa, but said that the Health Ministry has not approved the copy registration. He downplayed Eli Lilly's claim that recent layoffs in Turkey were in part to weaknesses in the intellectual property regime, claiming that most of those laid off or reassigned were sales and marketing personnel.

Comment

¶9. (SBU) Comment. The local EU Delegation and the Belgian Embassy (the local representative of the EU Presidency for economic issues), have told us that they share our views on the shortcomings of the new regulation. In their presentations to the Turks, they highlight the inconsistency of the law with Customs Union obligations. The EU will raise the issue at a regular bilateral Turkey-EU meeting under the Customs Union that will be held in Brussels at the end of February. (This may account for the slightly more equivocal position we heard at the FTU.) The EU Delegation has been attempting to assess the commercial impact of the loophole on retroactive application, but has not received useful information on pending applications from the Health Ministry. The EU representatives have not responded to Embassy's suggestions that we jointly raise these issues with the Turks.

¶10. (U) Embassy also plans to deliver ref (A) demarche to MFA and possibly other GOT agencies involved in pharmaceuticals policy. We will also provide input on this issue septel for the Special 301 review process.

Edelman